

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2236705	(X3) Date Survey Completed 07/06/2022
Name of Provider or Supplier Njin Of Rutherford	Street Address, City, State 69 Orient Way, Rutherford, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the CareStart Covid-19 Antigen Test and interview with the Vice President of Operations (AVPO) via Telephone on 7/28/22 the laboratory failed to follow the Information For Use (IFU) when performing Covid tests from September 2021 to the date of the survey. The findings include: 1. The IFU stated " Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate. " but the laboratory did not report test results to relevant public health authorities. 2. The laboratory performs approximately 5 COVID tests per month. 3. The AVOP confirmed on 7/28/22 at 11:14 that the laboratory did not follow the IFU.</p>
D1002	<p>REPORTING OF SARS-CoV-2 TEST RESULTS</p> <p>During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the Carestart COVID-19 Antigen Test system and interview with the Office Manager (OM), and Associate Vice President of Operations</p>

(AVPO) via telephone on 7/28/22, the laboratory failed to report all SARS-CoV-2 test results from September 2021 to the date of survey. The findings include: 1. The AVOP stated they were "unaware they had to report COVID-19 test results" to the State of New Jersey. 2. Approximately 5 patients are run monthly. 3. The AVOP confirmed on 7/28/22 at 11:14 am the laboratory failed to report all SARS-CoV-2 test results.